



Implications of the COVID-19 pandemic for patient safety

A rapid review





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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CDC	United States Centers for Disease Control and Prevention
COVID-19	coronavirus disease
HIV	human immunodeficiency virus
MRSA	meticillin-resistant staphylococcus aureus
OECD	Organisation for Economic Co-operation and Development
РАНО	Pan American Health Organization
PPE	personal protective equipment
SDG	Sustainable Development Goal
TrACSS	Tripartite Antimicrobial Resistance Country Self-assessment Survey
UNICEF	United Nations Children's Fund

Key observations

- 1. The COVID-19 pandemic revealed a range of safety gaps across all core components of health systems, at all levels.
- 2. The risks and magnitude of avoidable harm from the COVID-19 pandemic still need to be understood.
- 3. Disruptions to systems and processes of care affected previously known safety risks and sources of harm in health care and introduced new ones.
- 4. The capacity of health systems to continue the delivery of essential health services has implications for patient safety.
- 5. Managing COVID-19 in countries experiencing fragility, conflict and violence has been even more challenging.
- 6. The pandemic caused substantial disruptive impacts on the health workforce.
- 7. Misinformation and disinformation have been prevalent during the pandemic.
- 8. Safety and equity are inextricably linked, and the pandemic exposed long-standing structural drivers of health inequities and gaps in outcomes for certain population groups.
- 9. Interaction between patients and families and health workers was severely constrained.
- 10. While most of the consequences have been negative, several positive developments have also occurred.

CHAPTER 1

Background

1.1 Patient safety as a global health priority

Patient safety is a global public health issue that is of importance to all health systems around the world. It is foundational to health care delivery and essential for progress towards universal health coverage and achieving the United Nations Sustainable Development Goals (SDGs) (1). Unsafe health care can have tragic consequences for individual patients. Yet unsafe care also has far-reaching consequences beyond the individual level. A lack of focus on patient safety has major financial implications for both high-income countries and lowand middle-income countries. Prior to the COVID-19 pandemic, an estimated 134 million adverse events occurred annually due to unsafe care in hospitals in lowand middle-income countries alone, and were estimated to contribute to 2.6 million deaths (2). Unsafe and poorquality care were greater barriers to reducing mortality than insufficient access, with 60% of deaths from conditions amenable to health care being attributable to unsafe and poor-quality care, whereas the remaining 40% of deaths resulted from the non-utilization of health services (3). Nearly 15% of hospital expenditure and activity could be attributed to treating safety failures in Member countries of Organisation for Economic Cooperation and Development (OECD) (4).

The COVID-19 pandemic has had a substantial impact on the capacity of health systems to continue the delivery of essential health services. Health care delivery underwent substantial disruptions and ad hoc redesign. Whereas the disruption of systems and processes affected previously known safety risks and harm in health care, it also introduced new ones. Disparities between high-income and low-income countries and the risks to vulnerable populations were exposed. The current pandemic continues to generate multiple challenges for patient safety within a broader sociotechnical system context, at the same time revealing the potential regarding future directions in patient safety improvements at both policy and practice levels. This becomes particularly important and timely for effective implementation of the Global Patient Safety Action Plan 2021–2030 (*5*), endorsed by the Seventy-fourth World Health Assembly in May 2021 by decision WHA74(13), which recommends incorporating patient safety in emergencies and settings of extreme adversity, and emphasizes the need for building high-reliability health systems and health care organizations that protect patients from harm in these situations (*6*).

1.2 Objective of the rapid review and target audience

The pandemic has highlighted the high risk of avoidable harm to patients, health workers and the general public, and exposed a range of safety gaps across all core components of health systems. These risks and harms need to be better understood. A deeper understanding of this knowledge can lead to improvements in health care delivery and to building safer and more resilient health systems in the future. With this rationale, the rapid review explores the following two questions:

- What impacts did the COVID-19 pandemic have on patient safety in terms of risks and avoidable harm, specifically in terms of diagnostic, treatment and care management related issues?
- 2. What are the main patterns of these implications within the broader health system context?

The target audience includes policy-makers, health care leaders, programme managers and health care facility managers and researchers. At the time of completion of this rapid review (May 2022), the pandemic is still not over and hence the implications summarized here build on the evidence and lessons learned from the prior two years to inform the path forward.

1.3 Methodology

A narrative rapid review approach was used for evidence synthesis (7). The narrative review format allowed a comprehensive analytic approach that was needed to gain an in-depth understanding of the broad range of issues posed by the pandemic (7). The rapid review takes a broad sociotechnical systems approach (8, 9) (that is, taking into account both technical and social contextual factors pertinent to patient safety, and considering interactions between people, technology and workplace, to outline patient safety implications arising from the COVID-19 pandemic). It incorporates risks and avoidable harm to patients, health workers, and the general public (10).

A literature search was conducted during December 2021 and March 2022 which involved analysis of both published and grey literature, and a comprehensive review of existing World Health Organization (WHO) publications and two international patient safety websites that catalogued patient safety literature related to COVID-19 (COVID-19 and Patient Safety (pipsqc.org and https:// psnet.ahrq.gov/). Materials available through blogs and webinars, as well as reports produced by other international organizations, were also reviewed, and expert opinion was obtained through a consultative process, including virtual expert consultation panels and iterative reviews. Considering the broad and multidimensional scope of the topic, spreading across several disciplines, health care settings, and countries, a diverse expert group provided input for initial scoping of the rapid review, including the key domains and themes and the types of impacts and implications to be researched.

Broad representation within the expert group ensured diverse perspectives, and included input from lowand middle-income countries, patients and their representatives, and internal WHO experts. The rapid review acknowledges limitations of available data, including the constraint that safety-related data from lowand middle-income countries was limited, and several available studies involved a single country or single site.

1.4 Outline of the rapid review

Using a pragmatic narrative review approach, the structure of this rapid review is based on the adapted WHO Health System Framework (11), identifying six interlinked thematic areas of implications that are broadly aligned with the health system building blocks (Fig. 1)

- 1. Health services
- 2. Health and safety of health workers
- 3. Patients, families and communities, including inequities
- 4. Leadership, governance and financing
- 5. Communication and management of health information

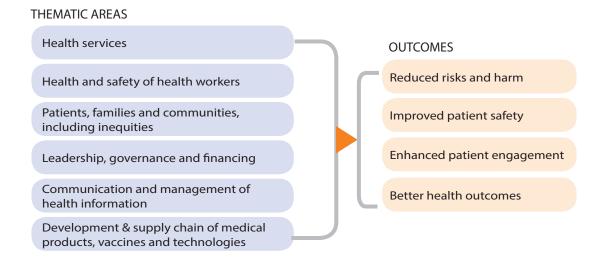


Fig. 1. Adaptation of the WHO Health System Framework to patient safety

6. Development and supply chain of medical products, vaccines and technologies.

The implications discussed herein reflect the challenges of the COVID-19 pandemic and its impact on patient safety. While the rapid review focuses largely on the negative impacts of the pandemic, there were several transformational changes and positive developments that also transpired. These transformative changes are described first, followed by sections that provide an overview of the implications of the COVID-19 pandemic for patient safety through a health system lens within each of the six thematic areas as listed above. The analysis highlights the consequences of risks and avoidable harm during the pandemic for patients, health workers and the general public. At the end of the rapid review, the key patterns of the implications are summarized, laying the foundation for follow-up work to generate more robust evidence and to support countries in their efforts to build safer and more resilient health systems.

Introduction

The COVID-19 pandemic continues to impact every facet of health care delivery systems across the world. Even before the COVID-19 pandemic, ensuring safe and high-guality health care had been challenging. With the unanticipated surge of COVID-19 cases, the pandemic has created an unprecedented demand for care leading to a global strain on health systems, most of which were not fully prepared to handle large-scale emergencies. The pandemic has emphasized the high risk of avoidable harm to patients, health workers, and the general public, and has identified a range of safety gaps across all core components of health systems at all levels. The impact of the pandemic is still unfolding and will have longterm ramifications. The disruptive and transformative impacts of the pandemic have confirmed patient safety as a critical health system issue and a global public health concern (12).

Patient safety requires resilient and reliable health care systems and processes. With the onset of the pandemic, health care delivery underwent substantial disruptions and ad hoc redesign when physical distancing and other public health prevention strategies were implemented in countries to minimize the risk of infection. The disruption of systems and processes introduced many safety risks (13). The surge in numbers of COVID-19 patients led to shortages in space, staffing and supplies, such as personal protective equipment (PPE) and oxygen. Some facilities adopted crisis standards of care, as occurs when resource shortages lead to decisions focusing on patient populations rather than on individuals (14).

The pandemic had several collateral impacts. Health care facility managers and health workers faced challenges of balancing routine appointments and elective procedures in the midst of surges, of prioritizing the urgent needs of patients with acute and chronic conditions unrelated to COVID-19, of mitigating the risks of diagnostic and treatment delays for all patients, and of protecting uninfected patients and staff from COVID-19. Consequences included staffing shortages and high levels of sickness absence (15), staff redeployment to new and unfamiliar roles and locations, limited resources, and changes in workflow due to COVID-19 (such as isolation, telehealth and workarounds to manage resource shortages). The resulting disruptions to existing care processes in health systems occurred worldwide and posed challenges to safety. The pandemic has impacted the capacity of health systems to respond, as well as their financial stability (16).

The rapid spread of a new disease and new treatments posed new risks to safety. Care delivery disruptions increased previously known risks and harm and introduced new ones. Problems with testing and contact tracing were common. Disruptions led to impacts on acute, chronic, and preventive care, and a decline in patients seeking routine medical care and screenings (17). Care delays arose from patients avoiding care due to fear of getting infected or of overloading already strained health systems. People were unable to get to the clinic or hospital due to specific public health and social measures, and patients with complex chronic conditions were unable to receive their routine ambulatory or preventive care due to overstretched health systems or because COVID-19 admissions were given higher priority (18). Patients experienced inequities in care (19). Diagnostic errors occurred relating to the diagnosis of both COVID-19 and other non-COVID conditions (20).

Health worker safety, which is fundamental for patient safety, has become more conspicuous because health workers are at a higher risk for SARS-CoV-2 infection (21) and have paid the toll for other consequences of their

professional role, such as high workload, stress, burnout, violence, harassment, stigma and discrimination during the pandemic (22). Both physical and mental health (23) and the security of health workers have been affected. There have been thousands of COVID-19-related preventable deaths among health workers (15).

New threats to patient safety related to leadership, communication, and information management also emerged during the pandemic. Communication in the midst of doubt became the norm among government and health care leaders at all levels, as well as in the scientific community, public and media. Decision-making sometimes relied on anecdotal cases and experiences rather than scientific evidence (24). There was less time for critical reflection on biases that influence thinking, on how to balance risk and how to critically appraise the evidence to manage an evolving health and public health crisis. Given the dynamic and emerging evidence

amid ambiguity, many people struggled to balance acting swiftly with creating potentially unnecessary panic. There were challenges in developing, evaluating and disseminating robust evidence, medications, and best practices for diagnosis and treatment amidst rapidly changing circumstances. An "infodemic" – too much information, including false or misleading information, spreading rapidly in digital or physical environments. It causes confusion and risk-taking behaviours that can harm health.

Overall, an understanding of patient safety implications is still evolving with the pandemic (25). However, based on the available evidence, it is clear that COVID-19 has caused a "perfect storm" in the field of patient safety, and heightened the need to have further research in the area and identify and implement initiatives that ensure safer care, especially in the context of outbreaks and emergencies.

Transformative changes

Despite a range of challenges to patient safety during the COVID-19 pandemic, there were several positive developments.

3.1 Leadership and culture

Several strategies and leadership engagement initiatives facilitated communication, decision-making and coordination (26). When COVID-19 was perceived as a "common enemy", silos between people, institutions, industries and countries often broke down (26). Incident command systems were developed across many hospitals and health care facilities to facilitate rapid emergency response, communication, coordination and decision-making (27). There was widespread sharing of clinical information and best practices within and across organizations, more standardization than before, and rapid development of evidence. In countries with limited human, infrastructural, and financial resources, hospitals documented and shared in real time their experiences to inform more pragmatic policy-making and to help develop future standard operating procedures and service delivery practices (28, 29).

3.2 Vaccines, diagnostics and therapeutics

The rapid development of vaccines, diagnostics and therapeutics is one of the greatest achievements of science. Clinical trials were expedited, and several novel vaccine platforms were rapidly developed and deployed (*30*). To provide independent assessment of the potential causal link between adverse events following immunization and COVID-19 vaccination, several

countries (31–34) established and further strengthened their expert committees on adverse events following immunization in the light of experiences during the COVID-19 pandemic. For the first time experts from other fields, or so called non-traditional experts, were included in such committees.

3.3 Service delivery transformations

Several other pandemic-related transformations and innovations also occurred. There are many accounts of novel ways of re-engineering cross-sectoral working and the dissolution of silos. The speed of transforming service delivery was unprecedented. Rapid progress was achieved in the development of innovative crisis management programmes, the development of checklists for hospital emergency preparedness and response (35), and the adoption and modification of local policies and guidelines in line with the evolving circumstances and updated guidance of international agencies and professional organizations. New clinical protocols were deployed and implemented, best practices were shared, and risk prevention measures were adopted. Rigorous training of staff via online, automated, reality-assisted and blended training, including through the WHO Academy and other trusted providers in the digital space, involved improved methods for engagement to ensure understanding and implementation of new and emerging guidelines. New COVID-19 health care facilities, non-COVID patient areas, field hospitals, and equipment installations sprang up at a speed never seen before.

3.4 Awareness of overall health, self-care and digital literacy

The pandemic led to more public awareness of health and self-care, more digital literacy (36, 37), and more implementation of home care (38). Despite the strain, there were reports of positive patient experiences (39, 40), including one in which patient surveys showed appreciation for providers and caregivers in an analysis of open-ended comments (41). Though some studies indicated these positive developments, home care and patient experience are areas that need to be further researched.

3.5 Health worker safety

The pandemic raised awareness about mental health and the importance of caring for health workers (42). Health worker safety focus has long been underappreciated but is now improving, at least in some contexts, due to several support structures and best practices, including hotlines, psychological first aid training, town hall meetings, going-home checklists, and websites for complimenting colleagues. One third of countries have developed national regulations, policies or guidelines for occupational health and safety for health workers in the context of COVID-19 (43).

3.6 Industrial developments

Several industries adapted to manufacturing new items or increasing production of their existing items to ease the gaps between demand and supply. Many start-ups originated and helped with the supply of essential items to hospitals. People on the front line developed new and innovative solutions to specific problems posed by the pandemic. The spread of these innovations was also often rapid (44). Vendors and transporters increased their scale and hours of operations. COVID-19 brought the understanding of hospital infrastructure, the architectural design of health care facilities and the supply chain to the realm of safety of health care (45). Special task forces were established as countries rapidly upgraded existing vaccine production, licensing and delivery mechanisms (46).

3.7 Digital transformations and innovations

The pandemic accelerated new digital transformations and innovations related to new care pathways, diagnostic technologies, novel at-home diagnostic tools and strategies, and the use of predictive models and initiatives to learn from large-scale data and develop scientific evidence. It highlighted the importance of secure data exchanges across different care settings while upholding privacy, and the necessity of integrated data around one unique patient record. More digital communications between care providers as well as between patients and care providers were possible.

There was rapid implementation of digital consultations via telemedicine, which had previously stalled (47). Digital health services have shown the potential for making the delivery of health services more effective and user friendly for some groups of people, such as people living with physical impairments and chronic illnesses. One report suggested that patient satisfaction with and trust of telemedicine during the COVID-19 pandemic was high (48). Digital literacy played a fundamental role in users' confidence in accessing and using such digital health services.

3.8 Overall approach to managing the pandemic

There are also examples of countries that performed exceptionally well, given the circumstances. Several countries were able to institute better control at the national or regional level (49) and as a result performed better in combating the pandemic (50) and had better patient outcomes, at least within the first two years of the pandemic. The main factors identified as leading to improved control included rapid, science-based risk assessment with early and decisive government action and implementing interventions at various levels, such as border control measures, strong social distancing measures, expanding testing, case tracking and isolation, information sharing, setting up selective clinics and safe clinics outside hospitals for patient screening, and various community transmission control measures and casebased control measures (51–53).

Some countries had learned from previous experiences. In the case of the Republic of Korea, for example, the government had reformed the epidemic preparedness system after the Middle East Respiratory Syndrome outbreak in 2015 (52). One report attributed their positive experience to "national infectious disease plans, collaboration with the private sector, stringent contact tracing, an adaptive health care system, and governmentdriven communication" (54). The Republic of Korea used a multipronged strategy involving "centralized coordination and triage, local adaptation of key protocols and principles, and strong public health efforts to limit community transmission including physical distancing, contact tracing, and an aggressive approach to testing, isolation, and treatment" (55).

Safety risks and harm implications

The sections below describe the current state of knowledge of the implications of the COVID-19 pandemic for patient safety, across the six interlinked thematic areas (11).

4.1 Health services

Several ongoing patient safety activities were significantly interrupted when the COVID-19 pandemic disrupted existing systems and processes of care. Routine safety and quality meetings were stalled, and many safety and quality professionals were either redeployed from their administrative roles to clinical work or took on additional tasks (for example, procuring supplies and additional staff) in responding to the pandemic (56). This led to reduced resources, capacity and infrastructure to prevent and monitor known safety concerns.

Health care facilities often track adverse events and risks related to care, such as adverse drug events, health care-associated infections, patient misidentification, pressure ulcers, or procedure- and equipment-related issues. However, only some were able to respond rapidly to identified safety concerns using real-time processes to monitor, escalate and resolve them (*57*). At many facilities, external regulatory oversight (such as by payors and accrediting organizations) was withdrawn and less attention was given to routine safety and quality measures, including patient experience measures (*58–60*).

Many ongoing safety activities, such as safety analysis, mortality reviews, and hospital-wide safety and quality initiatives were stopped or delayed because of the pandemic. Moreover, the establishment of new sites for care expansion, such as field hospitals, created new risks because of rapid set-ups, high turnover of staff with different skills and experience, and new governance and safety standards (61).

Current systems for measurement and surveillance of patient safety are still not fully developed in most countries, at national or at institutional levels. While data from incident reports provide only part of the picture, they can be helpful in understanding harm and are commonly used for learning and improvements in patient safety. However, adoption of patient safety incident reporting and learning systems has been slow and not at the scale and speed of other high-risk industries, and only in some cases have the systems been made mandatory. Thus, available data on the measurement of errors and patient harm provide only a partial picture (62). Considering the fact that current systems for patient safety data collection and analysis are not robust, the exact burden of risks and avoidable harm during the pandemic cannot yet be fully assessed.

In the United States of America, the state of Pennsylvania has mandated safety reporting and has created the Pennsylvania Patient Safety Reporting System, which uses a secure, web-based system to enable health care facilities to submit safety reports. An analysis of 278 548 event reports submitted by acute care facilities in 2020 found a 5.3% decrease in reporting from 2019 (63). From April 2020 to March 2021, there was a 6.1% reduction in incident reporting in the National Health Service of England compared to the prior year (64). However, there was a 47.7% increase in incidents reported as deaths in the National Health Service from April 2020 to March 2021. Another study from the United Kingdom of Great Britain and Northern Ireland used the Safety Attitudes Questionnaire to measure safety culture at a large health care trust during the COVID-19 pandemic and found a significant decrease in error reporting after the onset of the pandemic (65). Thus, there may have been some reductions in safety reporting during the COVID-19 pandemic.

Substantial deterioration in multiple patient safety metrics has been observed since the beginning of the pandemic, with increases in adverse events including central lineassociated bloodstream infections, catheter-associated urinary tract infections, ventilator-associated events, and patient falls causing major injury and pressure ulcers (66).

While a lack of comprehensive data on safety events reduces insights about the impact of the pandemic, there have been useful publications. Several safety-related organizations have gathered early data to describe the negative impacts of the COVID-19 pandemic. For instance, in an analysis of 343 adverse events submitted to the Pennsylvania Patient Safety Reporting System between 1 January and 15 April 2020, the most frequently identified safety factors were related to laboratory testing (47%), process or protocol issues such as staff failing to use signin sheets to monitor interactions with COVID-19 positive patients (25%), and isolation integrity (22%) (67). Common outcomes were exposure to a patient with COVID-19 or under investigation (50%), and missed or delayed test follow-up (31%). An industry report compared nursing quality indicator data before and during COVID-19 and found an increase in stage 2 hospital-acquired pressure injuries, falls, and central line-associated bloodstream infections (68).

Adverse events are known to occur more frequently in patients isolated within a hospital, compared with nonisolated patients; in one study more than half were deemed preventable, with health care-associated infection as the primary cause (69). Isolation that was essential for infection prevention and control resulted in unintended consequences and adverse events. Data from the Pennsylvania Patient Safety Reporting System explored safety events that impacted patients with COVID-19 or those in isolation to rule out infection (70). The most common safety events, falls, and medication-related events. Among 484 event types, the most frequently identified were skin integrity (29%), falls (27%) and medication-related events (16%).

In one of the few studies on safety in primary care, a survey was used to examine patient safety incidents in primary care settings in France during the early months of the COVID-19 pandemic (20). Of the 132 reported

incidents, 44% related to delayed diagnosis, assessments and referrals. Reported incidents less commonly involved cancellation of care, home confinement-related incidents, and inappropriate medication discontinuation.

While more evidence of the impact on patient safety outcomes will be forthcoming, preliminary evidence and emerging reports are already showing concerning trends in the frequency of identification and the management of known safety events. These are summarized below.

4.1.1 Health care-associated infections

The pandemic resulted in substantial changes in infection prevention and control practices to enable the care of increasing numbers of patients amidst limited PPE, medical supplies and staffing (71). Reduced contact with patients with central venous catheters reduced the associated maintenance activities related to decolonization and line care needed to prevent infection (72). Emerging data from the 2020 National and State Healthcare-Associated Infections Progress Report (73) from the United States Centers for Disease Control and Prevention (CDC) suggest that ground has been lost in the progress made in the prevention of several important health care-associated infections in acute care hospitals. This included a 35% increase in the standardized infection ratio for ventilator-associated events, a 24% increase in central line-associated bloodstream infections, and a 15% increase in hospital-onset methicillin-resistant Staphylococcus aureus (MRSA).

Using data reported to the CDC's National Healthcare Safety Network, another study identified significant increases in national and state quarterly standardized infection ratios compared to 2019, and found significant increases in central line-associated bloodstream infections, ventilator-associated events. MRSA bacteraemia, and catheter-associated urinary tract infections in 2020 (74). A study involving 148 United States hospitals found 60% more central line-associated bloodstream infections, 43% more catheter-associated urinary tract infections, and 44% more cases of MRSA bacteraemia than expected over a seven-month period in 2020, based on predicted health care-associated infections had there not been COVID-19 cases (75). Health care-associated infections in England also remained high (76, 77).

After seven days in the intensive care unit, the risk of bloodstream infection was higher among patients

with COVID-19 compared to other critically ill patients (78). A study involving eight Italian hospitals found that critically ill patients with COVID-19 were at high risk for health care-associated infections, especially ventilator-associated pneumonia and bloodstream infections from multidrug-resistant organisms (79). Another study found that blood culture contamination and central line-associated bloodstream infection rates were significantly higher during the pandemic (January to May 2020) compared to rates prior to the pandemic (January to May 2019) (80). Possible reasons for increases in central line-associated bloodstream infection and catheter-associated urinary tract infection rates include longer length of stay, increased use of prone positioning, and changes in nursing practices in COVID-19 hospitalizations (81). In children, the odds of postoperative sepsis were higher during COVID-19 than they were prior to COVID-19 (82). Conversely, another study conducted in an intensive care unit in Singapore indicated that during the pandemic, higher nosocomial infection rates were seen in COVID-19 patients, but findings were not statistically significant (83).

There were several reports on nosocomial outbreaks of SARS-CoV-2 (84, 85), and one review found that the proportion of hospital-onset COVID-19 among hospitalized COVID-19 patients ranged from 0% to 15.2% (86). Patients with hospital-onset COVID-19 in the United Kingdom (compared to suspected community-acquired infections) were associated with a high risk of nosocomial transmission to other patients and health workers (87). Nosocomial outbreaks occurred for various reasons, including unmasked exposure among health workers, exposure to known infected patients, inadequate support to maintain universal masking adherence, and inadequate physical distancing (88). There were instances when inpatients contracted and died of COVID-19 while receiving care for a different condition (89). Nursing homes were particularly vulnerable, with an attack rate of 66% among residents and 45% among staff in a study from France (90).

Health care systems across the world experienced failures in infection prevention (19, 91) due to system constraints such as lack of availability of commodities, deficiencies in staff knowledge and skill, non-compliance with safe practices, and poor surveillance protocols, especially in nursing homes. Furthermore, the physical layout of many hospitals and clinics, including areas where staff gather and eat, did not ensure adequate amounts of physical distancing or adequate ventilation to protect against a virus increasingly recognized as airborne. Infection-related risks occurred despite proper use of PPE (92). In one instance in the United States, there was an outbreak of a multidrug-resistant fungal infection in a COVID-19 ward attributed to multiple factors, including extended use of the PPE underlayer and lapses in cleaning and disinfection of shared medical equipment (93). Additionally, there was excessive use of antibiotics throughout the pandemic (94).

4.1.2 Medication safety

Few studies addressed the issue of medication safety during the pandemic (95, 96). Safety issues related to medication use included inappropriate medication initiation, inadvertent stopping, and the lack of review of existing medications. Some of these were made worse by an absence of family members familiar with the patient's medication regimen. Independent doublechecks during medication preparation and dosing were often skipped or inadequately performed. The usual pharmacy workflow and operations were also impacted. For instance, medication orders in the hospital were often processed by pharmacists working at home, not in the hospital pharmacy. Technologies such as barcoding were used inadequately (97). There was widespread prescribing of alternative remedies for COVID-19 prevention and treatment that warrants additional study (98).

Additionally, many health workers were redeployed to address COVID-19 response requirements in new roles that in turn required training and familiarization with different safety workflows and processes (99). In one hospital, COVID-19-induced staffing changes were associated with a failure to engage barcode medication administration at the bedside, which resulted in several medication errors to patients (100).

To optimize use of PPE supplies and reduce health workerpatient exposure, hospitals sometimes kept patient infusion pumps in intensive care units outside patient rooms by using extended tubing (101, 102). This increased the risk of medications being given to an incorrect patient and incorrect medications being delivered and reduced the ability of the patient to verify the medication given. Inability to measure patients' weight during telehealth appointments led to incorrect dosages of weight-based medicines, such as chemotherapy (100). One study from China investigated the prevalence of adverse drug reactions in hospitalized patients and found it to be high (38%); the majority of these were drug-induced gastrointestinal and liver disorders. Length of stay, number of medicines used in the hospital, and underlying disease conditions were independent risk factors. The use of unproven medications for prophylaxis and treatment of COVID-19 also harmed patients (99, 103, 104).

Access to appropriate treatments remained challenging. Furthermore, many patients with COVID-19 received antibiotics, often inappropriately, thereby increasing the long-term threat of antimicrobial resistance (*105*). Several reports documented an increase in multidrug-resistant organisms during the pandemic (*106*).

4.1.3 Diagnostic errors

Diagnostic errors involved patients with COVID-19 and non-COVID-19 conditions. COVID-19 diagnosis could be missed due to false-negative test results or application of screening methods that are used widely at the entrances to public gatherings, events and hospitals. The pandemic has further increased the risk of diagnostic errors for several reasons. The disease itself was new, and knowledge about its clinical manifestations continues to evolve (107). Symptoms of COVID-19 and its complications can be easily confused with other illnesses (108). Many health and care workers are physically and mentally exhausted, and this influences their clinical decision-making. Communication challenges further increase the risk of diagnostic errors and delays in diagnosis (109, 110).

System factors such as understaffing, health worker maldistribution and lack of capacity for supportive supervision influence decisions in busy, chaotic and time-pressured environments (111). Several new types of cognitive errors have been described as occurring during the pandemic (112). In one study of event reports within a large United States health care system, the majority of diagnostic errors or delays were related to system strain (113). In an unpublished study from Colombia that analysed diagnostic errors in a cohort of patients hospitalized for non-COVID-19 conditions during the pandemic, the incidence of diagnostic errors was high (16.7%) ([Riano-Sanchez L, Puerto-Lopez J, Cano-Arenas N, Singh H, Cortes J], [Universidad Nacional de Colombia], unpublished data, [2022]). Nearly 40% of patients with diagnostic errors in this study experienced significant harm.

Additionally, use of PPE and isolation makes it harder to have clear and unambiguous communication, thus increasing the risk of all types of medical errors. One survey of a network of 72 United States hospital medicine groups showed how inpatient care activities, such as medication administration or phlebotomy, were often clustered together and involved technology (such as video interactions) to communicate with and evaluate patients (*114*). As a result, in-room encounters were significantly reduced, and diagnostic errors were more common. Nearly half of respondents reported non–COVID-19 diagnoses that were initially unrecognized in patients admitted for COVID-19 evaluation, and a similar number reported delayed identification of COVID-19 in patients admitted for other reasons.

4.1.4 Surgical safety

The pandemic led to a substantial restructuring of surgical care protocols (115) and postponement of surgical procedures. One study of 20 006 surgical patients in 61 countries found that public health and social measures led to one in seven patients not undergoing planned surgery and experiencing longer preoperative delays (116). A study from public sector teaching hospitals in Pakistan identified several themes related to patient safety challenges in surgery, including inadequate training for COVID-19 prevention, testing issues, PPE supply shortages, challenges in maintaining physical distance and prevention protocols, shortages of human resources, and teamwork and other communication issues (117).

A meta-analysis that included publications from December 2019 to June 2020, mainly from China, Spain, the United Kingdom and the United States, showed a remarkably high 20% postoperative mortality rate and 15% postoperative intensive care unit admission rate among COVID-19 patients (*118*). A study in the United States involving 10 940 surgical patients revealed that COVID-19 infection positivity was an independent risk factor for increased perioperative mortality. The overall mortality rate (14.8%) in the COVID-19 cohort was more than double that in the cohort without COVID-19 (7.1%) (*119*). In the United Kingdom, certain patients operated on between 12 March and 12 May 2020 were at higher risk of contracting COVID-19, and patients operated on at a COVID-free facility had fewer complications (*120*).

4.1.5 Patient falls

Two studies suggested an increase in the incidence of patient falls. The first study from Taiwan, China, conducted between January and May 2020, showed a three times increase in the in-hospital patient fall incidence rate compared to the same time period in 2019 (121). In the second study, a nationally representative online survey of over 2000 United States adults in January 2021 suggested that the COVID-19 pandemic was associated

with worsened physical functioning and fall outcomes, with the greatest effect on adults with reduced physical activity and social isolation (122).

4.1.6 Pressure injuries

Intrinsic factors related to the virus pathophysiology and extrinsic factors that overwhelmed health care systems increased the risk and incidence of avoidable pressure injuries (123, 124). Prior efforts to reduce hospital-acquired pressure injuries allowed one United States hospital to rapidly adapt existing workflows and processes, resulting in no increase between March and July 2020 (125). There were two additional types of pressure injuries during the pandemic: those caused by protective devices, and others caused by the prolonged prone position in respiratory patients undergoing treatment (126, 127).

4.1.7 COVID-19 immunization errors

Early in 2021, WHO alerted COVID-19 vaccine stakeholders of the possibility of potential immunization errors that could cause harm, and of the need to ensure patient safety (128). The potential errors that could occur with COVID-19 vaccines include incorrect site of vaccine administration, incorrect route (that is, a route other than intramuscular), vaccine administered to an unauthorized age group, wrong vaccine, wrong formulation or dosage, issues related to storage and vaccine handling, incorrect intervals between dosages and using incorrect diluent (quantity, type or using only diluent without the vaccine) (129).

During the COVID-19 vaccine roll-out, documented errors have been reported at the administration stage and the preparation stage (130–132). Organizational issues were the main cause behind such events happening, particularly at vaccination sites that used different types of vaccines. Other challenges included not seeking information on contraindications or reasons that would affect patient suitability for vaccination, and not applying immunization best practices (133).

4.1.8 Antimicrobial resistance

The ongoing COVID-19 pandemic threatens to magnify the emergence and spread of antimicrobial resistance due to misuse and overuse of antibiotics, increased transmission of microbial infections, and health service delivery interruptions. Disruptions of health services during the pandemic caused interruptions to treatments, such as for tuberculosis and human immunodeficiency virus (HIV), which could also lead to drug resistance.

Results from a rapid review that included 18 reports published between 2003 and April 2020 showed that only 8% of hospitalized COVID-19 patients experienced a bacterial or fungal infection, yet 72% of those patients received antibiotic treatment (134). Hospital admissions increase the risk of health care-associated infection and the transmission of multidrug-resistant organisms, which in turn leads to increased antimicrobial use.

In the 2021 Tripartite Antimicrobial Resistance Country Self-assessment Survey (TrACSS), 93% of respondents (from 151 countries) said that COVID-19 had impacted the development and implementation of antimicrobial resistance national action plans, including government commitment and technical operations (135).

4.1.9 Other hospital-associated risks

Despite prophylactic anticoagulation, patients with COVID-19 had a high risk of hospital-associated venous thromboembolism, also known as hospital-associated thrombosis (136). Indeed, later studies showed that the rates of hospital-associated thrombosis were the highest ever seen in infection (137). An increased frequency and complexity of rapid response team activations for respiratory distress was reported during the COVID-19 surge (138). A systematic review of literature about inhospital cardiac arrests showed a high rate of cardiac arrest in COVID-19 patients: in-hospital cardiac arrest incidence varied between 1.5% and 5.8% among hospitalized patients and between 8.0% and 11.4% among patients in intensive care units. Those patients had a mortality rate of over 90% (139). The reasons for the frequency of failure to rescue are not clear. Additional data are needed for assessment.

4.1.10 Telehealth-related risks and harm

As telehealth was rapidly deployed to care for patients, new safety concerns arose that required monitoring to ensure that telehealth had maximal benefits for patient outcomes (140, 141). These safety concerns included diagnostic errors (such as from inadequate or lower-quality history or physical exams) or medication errors (such as from inadequate or lower-quality medication reconciliation) (142).

Telehealth allows remote evaluation that protects both patients and providers who need to keep physical distance. Both parties appreciate its availability, general safety and convenience. However, absence of in-person evaluation, the need for specialized training, a new language for patients to describe their symptoms, the need for exceptional communication skills, and other factors raise new concerns about the process of making a "telediagnosis", defined as "coproduction of an accurate and timely explanation of the patient's health problem through remote interactions and transmitted data, including the clear communication of that explanation to the patient through these interactions" (143). The impact of telehealth on accurate and timely diagnosis warrants further evaluation, especially when patients present with new symptoms. For instance, clinicians need to recalibrate their thresholds for converting a patient's evaluation to an in-person visit (144). An incomplete or inaccurate physical examination and virtual patientprovider interaction can impact diagnostic accuracy (145). Diagnostic accuracy for the different types and severities of diagnoses that typically present to primary care clinicians via telehealth is still unknown (146). Both the challenges and opportunities for improving diagnosis during telemedicine interactions need additional evaluation (147, 148).

Meanwhile, several unintended consequences related to logistical aspects of the provision of telehealth have emerged (145). These include risks arising not only from inadequate infrastructure, such as insufficient quality of data transmission or poor internet connection, but also from insufficient competency-based training and administrative support, patients not understanding the treatment, inappropriate monitoring, inadequate language services, and health privacy issues related to the exchange of personal health information over the internet (145). Additionally, internet access remains a prominent barrier for some patients and populations.

4.1.11 Safety concerns from COVID-19 diagnostic testing

Laboratory systems preparedness, the complexity of molecular testing equipment and procedures, the availability of qualified personnel, and the availability and timely delivery of supplies and reagents were some initial universal problems. Many of these issues were accentuated in low- and middle-income countries. Throughout the pandemic and in many countries, lack of access to testing, delays in obtaining COVID-19 test kits and reagents, delays in obtaining test results and safety concerns over false-negative test results persisted throughout the pandemic. Several vulnerabilities emerged in the laboratory diagnosis of COVID-19, such as sample misidentification, inappropriate or inadequate sample collection, sample contamination, and the diagnostic accuracy of tests (149). In a report from the United States of America Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Organization Program, testing issues were the second most common type of patient safety concern identified. Concerns included a COVID-19 test not being performed, ordered, or sent properly, and involved inadequate screening procedures, failure to collect the swab, miscommunication between staff on testing procedures, and a lack of feedback from the laboratory on test results (150).

4.1.12 Collateral effects of care disruption

In addition to care in hospitals, COVID-19 led to the substantial disruption of services in all sectors and settings, including community-based interventions, primary care, emergency, critical and operative care, rehabilitative, palliative and long-term care, and auxiliary services.

There was a negative impact not just on COVID-19-related care but also on care related to other communicable and noncommunicable acute and chronic diseases, neglected tropical diseases, immunization, reproductive, maternal, newborn, child and adolescent health, and nutrition (13, 151-154). For instance, routine scheduled visits, prescription renewals of medications for chronic diseases, referrals to specialty care, elective and emergency surgeries, chemotherapy (155), urgent blood transfusion services (156, 157), laboratory and radiological services, antenatal and postnatal care, and management of moderate and severe malnutrition were all affected (158). Several delays were explicitly related to the cancellations of appointments or procedures. Potentially lifesaving emergency, critical and operative care interventions showed increased service disruptions, probably resulting in substantial near-term impact on health outcomes (159). Low- and middle-income countries were particularly vulnerable, with the risk of erasing any progress made in health care in the last few decades. In one report on Africa, authors cautioned that the disruption to critical health care services posed a serious threat to undiagnosed individuals, their local communities, and global health security (159). The pandemic increased the risk of undiagnosed individuals infecting others with HIV or tuberculosis, perpetuating the transmission

of pathogens causing neglected tropical diseases or succumbing to malaria or visceral leishmaniasis without treatment. Changes to essential public health functions and activities were also documented, with prevailing disruptions in disease prevention, health promotion, public health research, communications and social mobilization (159).

Collateral safety events that emerged from pandemic disruptions are discussed below.

4.1.13 Diagnostic and treatment delays from deferred acute care

One national survey of United States adults found that 41% of respondents avoided routine, urgent and emergent medical care during the pandemic (160). Avoidance of urgent or emergency care was significantly higher among unpaid caregivers for adults; persons with underlying medical conditions; persons with health insurance; non-Hispanic Black, Hispanic, or Latino adults; young adults; and persons with disabilities.

Several studies pointed to delays in acute care visits and potential deleterious effects related to fears of being infected, or because of health system strain due to a surge in COVID-19 cases. Patients' non-emergency appointments were put on hold to avoid spreading the virus and burdening health systems. In the United States, emergency department visits nationally were 42% lower for a four-week period (late March to late April) in 2020 than for a similar period in 2019 (161). Emergency department visits then subsequently increased, reducing the decline to 26% compared to 2019 for the last week of May 2020. The steepest drop-off in emergency department visits occurred in pandemic hot spots. Additional studies confirmed such findings (162).

In a study in the United States, the daily caseload of acute myocardial infarction, ischaemic stroke, non-traumatic subarachnoid haemorrhage and appendicitis dropped significantly (163). In the United Kingdom, deaths resulting from COVID-19 accounted for only half of the excess number of at-home deaths between April and May 2020 (164). Fewer patients presenting with medical emergencies combined with an increased number of non-COVID-19-related at-home deaths could suggest that patients may have waited too long to seek care. Another study in four hospitals in the New York University Langone Health system showed substantial reduction in non-COVID-19 hospitalizations for both chronic and

acute conditions and injuries between March and May 2020 (165). Emergency medical services in California, United States, reported the highest-ever number of cardiac arrests in the field in March 2020 – 45% more than in February – further suggesting that some of those patients had waited too long (166).

A report from Italy showed a significant decrease in acute coronary syndrome-related hospitalization rates across several cardiovascular centres in northern Italy during the early days of the outbreak (*167*).

The significant increase in mortality during this period was not fully explained by COVID-19 cases alone, implying that some patients died from acute coronary syndrome without seeking medical attention. In California, United States, an analysis from a large health system showed that the rate of hospitalization for acute myocardial infarction decreased by up to 48% between January and April 2020 (168). A survey in Spain found reductions in all interventional cardiology activities for acute myocardial infarction patients between February and March 2020, as well as reductions in the number of patients treated for myocardial infarction (169). In the United States, patients were also admitted for shorter times when comparing data from January 2019 till March 2020, suggesting that acute care was deferred or abbreviated (170).

Children also experience delays in acute care. A survey of paediatricians in the United Kingdom and Ireland on delayed presentations found that 32% of emergency department paediatricians and 18% of paediatricians working in inpatient or clinic settings had witnessed delayed presentations over the previous 14-day period (171). The most common delayed diagnoses were diabetes and sepsis, and in nine deaths the physician considered the delayed presentation to be a contributing factor. Evidence about appendicitis in children was mixed. In one study from Spain, there was no increase in the incidence of complicated appendicitis, and children with complicated appendicitis did not have worse clinical outcomes (172). In two studies that compared peak pandemic times to the prior year (one from the United States of America and another from Israel), patients presented with more severe disease and experienced suboptimal outcomes during the pandemic (173, 174). In Denmark, several instances of delayed care led to children being seriously ill with life-threatening conditions (175). Due to problems with accessing appropriate and timely care, there was a significant increase in diabetic ketoacidosis and its severity in children presenting with new onset diabetes during 2020 in Canada (176, 177).

4.1.14 Diagnostic and treatment delays from disruptions in routine care

Patients with chronic health needs and their clinicians faced substantial challenges during the COVID-19 pandemic. In England and Wales, surgical volume was reduced by 33.6% in 2020, which resulted in more than 1.5 million cancelled operations (*178*). Data on clinical pathways from England show that 4 million fewer people completed elective treatment in 2020 compared with 2019, and patients who needed to be hospitalized for treatment were waiting longer (*179*). The impact of waiting lists for elective procedures, surgeries and other elective treatments on patient outcomes is still unfolding.

Patients who needed evaluation for cancer were especially impacted. Survey results from 356 oncology care centres across 54 countries indicated that the impact of the pandemic on cancer care was widespread (180). Most centres (88.2%) reported facing challenges in delivering cancer care during the pandemic. Many centres reported a reduction in services, lack of PPE, staffing shortages, and limited access to medications. Nearly half of the centres reported missing at least one cycle of therapy in over 10% of patients. Harm occurred from interruption of cancer-specific care (36.5%) and non-cancer-related care (39%), with some centres estimating that up to 80% of their patients were exposed to harm.

An Italian study compared the same 10-week period in 2018, 2019 and 2020 in seven hospitals and found that cancer diagnoses fell by 45% in 2020, with the largest decrease being in colorectal, skin, prostate and bladder cancers (181). Similar delays in paediatric cancer diagnosis in Italy were also described (182). Substantial disruptions in paediatric cancer diagnosis and management occurred, particularly in low- and middle-income countries (183).

In the United States, there was a significant reduction in newly identified patients with eight common types of cancer during pandemic periods (184). Veterans Affairs Healthcare System facilities nationwide experienced substantial reductions in the procedures used to diagnose cancer and subsequent reductions in new diagnoses of cancer across the United States from 2016 to 2020 (185).

Studies in the United Kingdom modelled the impact on cancer survival of different scenarios of the COVID-19 accumulated backlog in cancer referrals due to public health and social measures (186). Another study in the United Kingdom projected that for many cancer patients,

treatment delays of two to six months would lead to a substantial proportion of patients with early-stage tumours progressing from having curable to incurable disease (187). It suggested that even small delays (for example, two months) would lead to substantial reductions in survival among younger patients. Some of these outcomes are now being confirmed. A study on cancer stage migration from Turkey found that during the pandemic, patients with inoperable or metastatic disease increased, whereas patients diagnosed via screening methods decreased, and 90-day mortality after cancer diagnosis was significantly higher (188).

Diagnostic and treatment delays also occurred for other conditions in the United Kingdom (189). Another study evaluated primary care use and subsequent diagnoses among residents in a poor urban area in the United Kingdom and found a 50% reduction in expected diagnoses for mental health conditions, and a reduction in medication prescriptions for cardiovascular diseases and type 2 diabetes.

In Italy, the treatment of cancer patients was substantially impacted. Many cancer outpatient visits were replaced by telephone consultation, and routine therapy, tests, and procedures were deferred (190). A study from Spain observed a decline in new diagnoses across all diagnosis groups, suggesting the presence of a large number of untreated and undetected cases across many conditions (191). Excess deaths from HIV, tuberculosis and malaria are projected to occur as a consequence of disrupted detection and treatment during the pandemic (192, 193).

A study from New Zealand suggested collateral effects, such as patients avoiding health care and downplaying symptoms, with possible delays in care (194). Staffing was stretched and there were increased numbers of people with mental health and social issues, and of people whose conditions got significantly worse because the COVID-19 pandemic delayed their care, including surgeries (195).

4.1.15 Impact from disruptions in preventive care, screening and immunization programmes

Service delivery ranging from routine preventive inpatient care to specialized preventive programmes has been disrupted (196). A study from Sweden evaluated missed nursing care and patient safety during the initial wave and found that nurses reported worse safety and

more missed nursing care in wound care and in basic nursing in COVID-19 patients (197). Preventive and routine dental care in the United States was delayed due to dental office closures, reluctance to seek care during a pandemic, and loss of insurance coverage (198). Some of these delays led patients to have untreated tooth decay or infections, some resulting in emergency department visits.

Several screening programmes were impacted. A systematic review found that colorectal cancer screening decreased in the range 28% to 100% in different countries and at different times after the onset of the pandemic (199). The total number of cancer screening tests received by women through the United States CDC's National Breast and Cervical Cancer Early Detection Program declined by 87% for breast cancer and 84% for cervical cancer during April 2020, as compared with the previous five-year averages for that month (200). Such prolonged screening delays may lead to delayed diagnosis, increased avoidable cancer deaths, and an increase in cancer disparities among women already experiencing health inequities. In the United States, nearly 10 million people missed screenings for breast, colon and prostate cancer between March and May 2020 (201).

Routine vaccination programmes have been disrupted. Nearly 23 million children missed out on basic vaccines through routine immunization services in 2020 (202). Persistent disruption in routine childhood vaccination has occurred, with certain groups affected disproportionately (203, 204). Estimates suggest that more than 100 million children could go without measles vaccination (205), and other preventable diseases could increase.

Interventions to control, eliminate and eradicate neglected tropical diseases have been severely disrupted (13). For instance, in several countries, staff assigned to rabies surveillance were redeployed to the COVID-19 response, and movement restrictions impeded rabies investigations (206). Delays in case-finding and mass drug administration are likely to lead to a resurgence of infection and disease, with populations living in areas that have intense transmission of schistosomiasis, trachoma or visceral leishmaniasis likely to be particularly affected (207). Existing models do not yet allow for quantification of the magnitude of these effects.

Interruptions to essential pregnancy, childbirth, postnatal and paediatric health care services due to COVID-19 have probably resulted in unintentional harm to children and to their mothers (208). A meta-analysis found that globally, maternal and fetal outcomes have worsened in 2020 during the COVID-19 pandemic and there was an increase in maternal deaths, stillbirth, ruptured ectopic pregnancies, and maternal depression (209). The review also found disparity between high-resource and low-resource settings. The COVID-19 pandemic negatively impacted the provision of respectful maternity care in several ways (210).

Risks for infants born to women with SARS-CoV-2 infection included preterm birth (211). A study from Nepal analysed outcomes before and during the enforcement of public health and social measures and found that institutional childbirth during the measures fell by more than half, institutional stillbirth rate and neonatal mortality increased, and quality of care was reduced (152). A WHO report identified early trends in utilization of health services from 2019 through 2020 and showed variance across countries in disruptions to antenatal care, facility births, and care-seeking for acute respiratory infections among children aged under 5 years (212).

Newborn care practices were impacted by reduced care-seeking and staff shortages. In one survey from 62 countries, mainly low- and middle-income countries, more than half of respondents reported that evidence-based interventions such as skin-to-skin contact were discontinued or discouraged, separation of the mother–baby dyad occurred, and follow-up care was disrupted (213).

A United Nations Children's Fund (UNICEF) survey in 77 countries found disruptions in health checks for children and immunization services, (214), while disruptions in antenatal check-ups and post-natal care occurred in a majority of countries. In a WHO survey, about a third of countries reported disruption to sexual, reproductive, maternal, newborn, child and adolescent health; in health services for children and adolescents; and in services for the management of malnutrition.

4.2 Health and safety of health workers

Health worker safety and patient safety are closely linked because health and safety risks to health workers can lead to risks for patients, patient harm and adverse patient outcomes (15, 215–217). Three global pulse surveys on the continuity of essential health services during the COVID-19 pandemic (August 2020, April 2021 and February 2022) confirmed that a lack of available health workers is the most common cause of disruptions to health services in the vast majority of countries, reconfirming the persistent health workforce challenges. The pandemic has had a substantial disruptive impact on the physical and mental health of health and care workers, including increased violence, stigma and harassment in the workplace and the community (42, 218). Many countries have experienced major gaps in response capacity, human resources and protective equipment that posed a high risk to health workers. In a number of contexts, and more acutely in low- and lower-middle-income countries, PPE supplies have been limited, and low-cost interventions such as face masks and water supplies for handwashing have proved challenging to implement (219). As of April 2022, based on 127 countries reporting to WHO, 70% of health workers have received primary series of COVID-19 vaccination. Physical distancing in overcrowded primary health care clinics has been challenging. A global survey of 5000 health workers carried out during the first wave of the pandemic demonstrated that the level of occupational risks in health settings were quite unacceptable for respondents, and measures for their prevention and control and for the management of occupational health and safety were largely perceived as insufficient (220).

Health workers and their households constituted a sixth of COVID-19 cases that were admitted to hospitals in Scotland (221). In one survey, nearly half of the health workers reported serious psychiatric symptoms, including suicidal ideation, during the COVID-19 pandemic (222). Despite increased emotional distress, Swiss health workers worried significantly more about patients, elderly people, and family members than about their own health (223).

Health workers have experienced several occupational health and safety risks. These include lack of adequate protection against the virus, limited or no PPE (224), challenges in training (21), lack of guidance (225), longer work hours, fatigue, burnout, anxiety (226), having to make difficult decisions about prioritizing care for seriously ill patients (moral distress or moral injury) (227), and fear amid a lack of adequate physical and psychological support (228, 229).

Approximately 70% of respondent clinicians working in Poland, Singapore and the United Kingdom reported feeling anxious, depressed or burned out (226). Burnout in this study was significantly inversely correlated with being tested for COVID-19 and perceptions of high levels of safety.

A survey in China reported that nurses, women and health workers who engaged directly in the diagnosis, treatment and care of patients with COVID-19 were at greater risk of depression, anxiety, insomnia and distress (230). A higher degree of burnout in nurses in Islamic Republic of Iran was correlated with a perceived higher number of adverse events in patients, and the reduced perceived safety and quality of care (231).

While several countries enabled changes to legislation in support of health workers, including more flexible professional licensing, credentialing, liability limits, and use of volunteer or retired clinicians (232), health workers have received variable levels of reassurance and support from colleagues and senior health system leaders. Many clinicians expressed uncertainty over whether their employers would support them if they got sick (233). A Swiss survey of health workers reassigned to COVID-19 units during the first wave of the pandemic showed that a lack of choice during reassignments can reduce intent to stay and workplace well-being, in particular if hospital management is not perceived to be responsive during the crisis. Attempts by hospital management to find solutions, such as flexibility in working hours or extraordinary leaves, can alleviate the perceived constraints of reassignment and be considered signs of responsiveness from hospital management (234).

WHO estimates that approximately 80 000 to 180 000 health and care workers may have died from COVID-19 between January 2020 and May 2021 (15). These numbers do not reflect the burnout or reduced well-being, mental health issues, suicides and suicide attempts, and emotional injury that health workers faced while taking care of extremely ill patients. It also does not include the toll on their families, who not only faced the risk of infections but also had concerns about the mental health and well-being of their health worker relative. Sometimes health workers had to make difficult decisions and provide both medical and emotional support for patients facing death in isolation – a complex burden that contributed to moral distress. Health workers reported fears of the unknown, of getting sick, and of bringing the virus home (235).

Conversely, vaccine uptake in health workers was not universal, further jeopardizing safety. In a study conducted by the Pan American Health Organization (PAHO) assessing the intention of health workers to get the COVID-19 vaccine as soon as possible (236), it was observed that 77% of the participants would receive the vaccine and 23% could qualify as "vaccine hesitant", with only 4% of respondents reporting that they never intend to get vaccinated. Nurses were classified as hesitant at a rate twice that for physicians, and younger age quartiles reported being more hesitant to receive COVID-19 vaccination than older age groups. Health workers who participated in the study expressed reservations about receiving new vaccines, specifically reporting a perceived risk of serious adverse effects that could cause harm in the long term.

Other occupational health risks amplified by the pandemic include prolonged use of PPE, violence, harassment, stigma and discrimination (22). A scoping review of adverse effects of prolonged PPE use among intensive care unit health care professionals during the COVID-19 pandemic reported skin injury, heat stress symptoms, headache, chest discomfort and dyspnoea as the most common symptoms (237). A survey of over 7000 people from 173 countries found that health workers were more likely to experience COVID-19-related harassment and stigma (238). Disruptions due to changes in work schedules, redeployment (239), and lack of adequate supervision and interprofessional collaboration (240) further reduced their job effectiveness and support mechanisms. Health workers faced a high cognitive load due to a deluge of new daily clinical information relevant to diagnosis and treatment, new policy updates to follow, increased training requirements, and pressures to change practice according to evolving requirements (241). These stresses can have a negative impact on patient safety processes and outcomes.

Pre-existing health workforce shortages have been exacerbated both by competing service demands and by direct impacts on health and care workers themselves. Significant staff shortages, redeployment to unfamiliar work environments, shortage of supportive supervision, and separation from team members threaten safety. The nursing workforce has experienced a particular staffing challenge and adverse nurse-to-patient ratios. In the United States, nurse under-staffing led to the increased use of safety workarounds (safety-related shortcuts), increased cognitive failures, and near misses (242). Nurses in New Jersey, United States, reported that they were understaffed, lacked access to ancillary staff, and struggled to adhere to essential patient safety protocols (243). At certain times, staff in the United States with COVID-19 were being asked to show up to work due to staff shortages (244).

While immediate workforce shortages have been acute and more visible as a result of the COVID-19 pandemic, it has also magnified pre-pandemic shortages and maldistribution. The effect of COVID-19 on health and care workers has medium- and long-term impacts on patient safety due to reduced opportunities for training, education and competency development. In some hospitals, bedside medical education was impacted by, for example, conversion of in-person lectures into remote learning, and clinical rotations in the hospital were either reduced or stopped.

Sometimes trainees were redeployed from their own specialty to another, and they provided care for general medical patients or backfilled others among staffing shortages. Medical education, including bedside medicine (245) and training related to elective surgeries and procedures, was impacted, potentially affecting the development of technical skills (246). The long-term impact on medical education, training, and continuous professional development will need to be comprehensively assessed and managed.

4.3 Patients, families and communities, including inequities

The COVID-19 pandemic affected all population groups, though there were differential exposures, risks and vulnerability leading to differing health outcomes and non-health-related consequences of the pandemic, largely due to the social determinants of health and preexisting chronic conditions. Interaction of patients and families with health workers was severely constrained as many services became virtual, thus compromising the quality of patient and family engagement and patient safety. Moreover, families were unable to provide support to each other because of the necessary social restrictions and visitation policies creating a safety net for errors and avoidable harm.

The pandemic exposed long-standing structural drivers of health inequities – as well as gaps in health outcomes – for vulnerable populations. Disproportionate disease risks were exposed relating to age, race, income, minority status, immigration status, domestic abuse, lack of health insurance or access to care, comorbidities, immunocompromised status, education level, type of employment and employment conditions, housing conditions, and living in a neighbourhood with higher levels of deprivation, among other factors (247). Support systems and programmes geared to respond to the unfolding crisis were not adequate for many populations (248) and many people are still missing out on essential first-contact care, with primary care

and community care among the most affected service delivery settings (159). Populations in rural and remote areas, already disproportionately experiencing health system performance deficiencies in many countries prior to COVID-19, have faced particular challenges in accessing COVID-19 and non-COVID-19 services during the pandemic.

The COVID-19 pandemic also highlighted the ethical issue of using unproven interventions for COVID-19 in the absence of a strong evidence-based risk-benefit profile. During the pandemic, several unproven interventions were used outside the research contexts. These included blood products (such as convalescent plasma) and certain medications proven to be safe and efficacious for conditions other than COVID-19 (such as hydroxychloroquine) and those that still had to be proven effective for COVID-19 (such as remdesivir). Although these have been used to address the issue of access to care – an approach that may be beneficial for patients in such exceptional circumstances – their use is also considered a challenge for patient safety (249).

In many countries, the COVID-19 response in rural areas has been hampered by inadequate numbers of appropriately trained health professionals; poor facilities and infrastructure, including limited capacity in rural clinics to treat severe disease manifestation requiring intensive care; shortages of key health products such as testing kits, vaccines and PPE; weak referral systems and inadequate safe medical transportation; and weak financial, geographical, and organizational accessibility of public services. Prevention of infections was harder in disadvantaged parts of any country, rural and remote areas, or low- and middle-income countries. Global inequities in the distribution of COVID-19 vaccines, with the bulk of vaccines now being used in a limited number of high-income countries, has further put at risk the health of the rural poor in low- and middleincome countries. Rural poor communities in low- and middle-income countries have also experienced negative impacts on their coverage of other services, from child health to HIV testing, while also experiencing significant deterioration of the social determinants of health (such as loss of income).

Managing COVID-19 in countries experiencing government fragility, conflict and violence was even more challenging because of unstable social and economic conditions, weak governance and state institutions, limited access to services for vulnerable populations, and public mistrust of government (250). All of this resulted in forgone care, delayed care, and lack of treatment adherence.

In the United States, people in hospitals and nursing homes and those who depended on behavioural health care services faced inequitable care problems and were adversely affected (251). In addition to disparities in care and outcomes, there were low levels of vaccination among vulnerable populations. This section summarizes the safety implications for patients, families and communities, and focuses on inequities and vulnerable populations.

4.3.1 Equity considerations

Largely due to the social determinants of health, subpopulations can face differential exposure to SARs-COV-2, differential vulnerability and access to safe and quality services, differential health outcomes, and differential non-health-related consequences as a result of illness and treatment (for example, stigmatization, lost work, and impoverishment) (247). From the equity and patient safety perspective, there are two pathways through which some patients may be at greater risk of harm:

the existence of supply- and demand-side barriers to access to health services, which may result in some populations not ever accessing services (unmet need) or delaying seeking treatment.

the inequitable distribution of inputs (such as medical products, well trained personnel, properly maintained equipment) required for optimal health system performance, whereby poorer, socially excluded subpopulations are more likely to use services that have suboptimal safety and quality, and thus be disproportionately exposed to safety risks and harm.

A WHO evidence brief elaborates how certain groups have experienced increased rates of COVID-19 morbidity and mortality, such as poorer people, marginalized ethnic minorities including indigenous peoples, lowpaid essential workers, migrants, populations affected by emergencies including conflicts, incarcerated populations and homeless people (247). A report from Public Health England found that "after adjusting for age, in the first wave of the pandemic, people from Black African, Black Caribbean, Bangladeshi and Pakistani ethnic backgrounds were at a greater risk of death from COVID-19 than the white British group" (252). In addition to occupation, risk factors associated with a higher risk of COVID-19 included "living in larger and/or multigenerational households with school-age children and living in high population density areas with poor air quality and higher levels of deprivation". Several epidemiological indicators, including from CDC and

PAHO, suggest that indigenous populations have been disproportionately affected due to COVID-19 (253, 254).

In a large study from Brazil, death from COVID-19 was associated with age, indigenous ethnicity, poor geopolitical region, and pre-existing medical conditions (255). The study found that disparities in care, poverty, and comorbidities amplified the burden of COVID-19 in more vulnerable and socioeconomically disadvantaged children and adolescents. Inequities also involved geographical regions because of underinvestment in health systems in disadvantaged parts of a country or region, including those in rural and remote areas.

A CDC report found disproportionate health outcomes in the United States, where people from racialized and ethnic minority groups had an increased risk of getting COVID-19 disease and dying from it (256). Many of these inequities were attributed to social and structural causes of illness and death (social determinants of health, which include factors such as socioeconomic status, neighbourhood and physical environment, education, employment, social support networks, and access to safe health care). Structural inequities were present and persisted long before the pandemic. A pre-pandemic analysis conducted in the United States found that Black adult patients were significantly more exposed to unsafe care relative to white patients in the same age group, of the same gender, and treated in the same hospital (257).

The United States of America Agency for Healthcare Research and Quality (AHRQ) analysed data from April to September 2020 and found that while there was a 17% decline in hospitalizations for non-Hispanic white patients and a 12% decline for non-Hispanic Black patients compared to earlier years (*258*), hospital deaths for any condition increased 15% for non-Hispanic white patients, 60% for non-Hispanic Black patients, and 135% for Hispanic patients compared to earlier years.

In the United States of America, for some subpopulations, an increased risk of serious illness with COVID-19 is due in part to higher rates of underlying comorbidities, such as diabetes, asthma, hypertension, and obesity, which are largely driven by the social determinants of health (259). They are also more likely to be uninsured and lack a usual source of care; more likely to work in service industries at risk for loss of income during the pandemic, or have a job not amenable to telework; and more likely to have a vulnerable housing situation, such as living in a multigenerational family home or low-income and public housing that makes isolation or distancing harder (260). The pandemic also highlighted racial and ethnic disparities in patients with mental health care needs. Blacks and Latinos in the United States had substantially lower access to mental health and substance-use treatment services even before the pandemic (261), and Black patients with substance abuse disorders have experienced increased rates of overdose in recent years (262).

People with psychosocial and intellectual disabilities in institutions, psychiatric hospitals and social care homes were at considerable risk of inequity (263). These settings are prone to outbreaks because of the difficulties of trying to implement physical distancing in often crowded settings, and other preventive measures not being effectively implemented.

Although COVID-19 vaccines were developed in record time during the COVID-19 pandemic, the vast majority have been administered in high- and upper-middle-income countries. Although WHO set a target for all countries to vaccinate 10% of their populations by the end of September 2021, 56 countries were unable to reach this target – most of them in Africa. More countries are at risk of missing the WHO targets of vaccinating 40% of their population by the end of 2023 (*264*).

4.3.2 Impact on patients in longterm care settings

Even before the pandemic, over half of the harm that occurred in long-term care settings was deemed preventable, and over 40% of admissions to hospitals from long-term care was deemed avoidable (265). While successful infection prevention and control occurred in several instances (266), long-term care settings have experienced infection control challenges and disproportionately poor outcomes. Residents in those settings are older with several chronic diseases and disabilities, and their physical environment includes multi-resident rooms that make distancing harder (267). They also have relatively low levels of staffing and low adoption of information technology, and traditionally have limited infection control supplies. Moreover, guidelines and standards developed for the prevention or surveillance of COVID-19 in hospitalized patients may not be generalizable or appropriate for nursing home patients (268). Additional risks included less access to family members who were integral to care, overworked staff, and reduced or suspended inspection schedules. Older adults with or without pre-existing chronic conditions are at higher risk of COVID-19 infection and are more likely to have severe cases that require intubation, ventilator

support and intensive care (267). A high proportion of nursing homes reported a severe shortage of PPE and staff shortages (269). One third of nursing homes in Italy reported at least one adverse event during the early weeks of the pandemic (270). Adverse events were more likely to occur in nursing homes with higher bed capacities, increased use of psychiatric drugs, and the use of physical restraints. COVID-19 has had a significant toll on people living with dementia in long-term care facilities or in the community (271–273).

4.3.3 Impacts due to visitation policies

During peak phases of the pandemic, families have been largely prohibited from visiting patients in hospitals and nursing homes, leading to major social and emotional consequences for both patients and families. In addition to psychological consequences for both patients and families, this has had new safety consequences, because family members often provide a safety net by identifying safety events and protecting against errors (274). Patients have experienced adverse events that could have been prevented or mitigated by the presence of families or caretakers. These events involve delays in diagnosis, problems with transition in care, falls and clinical deterioration that was not acted upon (275).

Hospitals that were closed to visitors experienced the most pronounced deficits in patient ratings of medical staff responsiveness, fall rates and sepsis rates (276). In another study, family visitation (in person or virtual) was associated with a lower risk of delirium (277).

4.3.4 Mental health impacts on the public from isolation and enforcement of specific public health and social measures

In a WHO survey, over 60% of 130 countries across the six WHO regions reported disruptions to mental health services for vulnerable people, including children and adolescents (72%), older adults (70%), and women requiring antenatal or postnatal services (61%) (278). An Organisation for Economic Co-operation and Development (OECD) report concluded that from March 2020 onwards, the prevalence of anxiety and depression increased and, in some countries, even doubled (279). There has been an increase in mental health conditions as a result of a combination of economic constraints, reduced access to mental health care resources, individual vulnerabilities, changes in lifestyle and social

stigma against COVID-19 patients and their family members (280, 281). Many people with mental health conditions are already isolated and rely on social and other services as a connection to the community. With the COVID-19 pandemic many of these services (such as home visits) ceased, isolating people further. The effects of isolation extended far beyond the hospital. Both anxiety and depression among the public were found to be common (282).

Individuals with substance use disorders are at an increased risk of contracting COVID-19 and are more likely to experience poor outcomes if infected (283); although protected by vaccination, they nonetheless have a greater risk for breakthrough infections than vaccinated individuals without substance use disorders (284). A recent WHO rapid assessment (154) found significant disruption of services for people with substance use disorders during the COVID-19 pandemic. For example, there was full or partial disruption of opioid agonist maintenance treatment programmes in 45% of countries; of overdose prevention and management programmes in 53% of countries.

4.3.5 Linkage between poor mental health and avoidable harm

Mental health impacts have potential downstream consequences for patient safety, including increased use of substances and medications, surges in people visiting emergency services for help with behavioural health issues that may lead to overcrowding and delays (285), and harm, including self-harm. Cases of domestic violence have grown worldwide, especially violence against women (286, 287). One study reported that frequency of suicide and self-harm cases in the emergency department increased during the initial phase of the COVID-19 pandemic in Nepal. In a CDC analysis, worse mental health outcomes, increased substance use, and elevated suicidal ideation were found in younger adults, racial and ethnic minorities, essential workers, and unpaid adult caregivers (288). More data are needed to assess the impact on suicide rates (289). Social distancing and isolation measures implemented in response to COVID-19 coincided with an increase in aggression incidents among people with intellectual disabilities (290) and were detrimental to patients who face addiction (291).

Children have been at particular risk from isolation. Their mental health and well-being has been substantially affected by the pandemic (292). Prior studies show that

children isolated or quarantined during a pandemic are more likely to develop acute stress disorder, adjustment disorder, and grief (293). A meta-analysis estimated that one in four youths globally are experiencing clinically elevated depression symptoms, while one in five are experiencing clinically elevated anxiety symptoms; both estimates increased over time and are double that of prepandemic estimates (294). Data suggest a substantial increase in suicide attempts in children in late 2020 and early 2021 in France (295).

In 2020, mental health-related emergency department visits among adolescents increased by 31% compared with 2019. In 2021, there was a similar increase in emergency department visits for suspected suicide attempts among adolescent girls (50.6%) and adolescent boys (3.7%) compared with 2019 (296). The longer-term mental health and economic effects of the pandemic will require reassessment (297). Additional impacts on children include firearm-related encounters, which increased in the United States significantly between March and August 2020 (298), and increasing cases of child abuse (299, 300).

4.3.6 Post-COVID-19 condition

Post-COVID-19 condition (301) in patients with confirmed or suspected COVID-19 who continue with prolonged and debilitating symptoms months later, referred to informally as "long COVID", raises additional safetyrelated implications. (302). In the United Kingdom, an estimated 945 000 people self-reported long COVID, with the greatest prevalence in people aged 35-69 years, girls and women, and those living in the most deprived areas, working in health or social care, and with another activity-limiting health condition or disability (303). Post-COVID-19 condition impacts a large number of patients and raises additional safety-related concerns related to diagnosis and treatment that require monitoring and further study. WHO has called on countries to prioritize recognition, rehabilitation, and research to improve outcomes for these patients.

4.4 Leadership, governance and financing

The COVID-19 pandemic has been one of the greatest tests of health care leadership at all levels – national, subnational, local and organizational. During the pandemic, leaders needed to establish clear and transparent lines of communication at every level, implement teamwork principles, build trust, reinforce the use of universal precautions, ensure the use of best practices and keep up with dynamically changing guidance (12). COVID-19 also required leaders to take a far more proactive stance and collaborate with other health care organizations as well as with public health and government officials. In addition to leaders, mid-level managers also played a significant role in managing the pandemic as well as its direct and collateral impacts on safety.

The public health emergency required leaders to be agile, adapt, transform, and reorganize existing guidelines and practices to meet emerging requirements (304). Health care organization resilience in terms of capability to continue operations during the crisis was stretched. Having made relatively few pre-existing investments in high-reliability principles, many health systems and their leaders were caught off guard. The pandemic exposed vulnerabilities related to leadership (305), regulatory capacity, system preparedness, resilience and intersectoral collaboration (306).

Leaders had to balance responding rapidly amidst dynamic and emerging evidence in the midst of chaos and uncertainty (307). Leaders made decisions to prioritize resources, affecting how access to care was provided for both COVID-19 and non-COVID-19 patients. Sometimes these decisions were made without transparency, often without engaging patients, families and communities, and often in the context of complex policies and external, including political, pressures.

Leaders also played a critical role in helping to shape the experiences of health workers (308). One study in the United States identified six themes for positive leadership response and support of health workers during the pandemic (309): (a) effective communication and transparency; (b) prioritizing the health and safety of health workers; (c) employee scheduling considerations, including autonomy, assignment support and respite; (d) appreciation, both financial and non-financial; (e) showing up and listening; and (f) providing resources. All of these have safety implications. Actions and behaviours of leadership in implementing initiatives that support frontline health workers are essential (310). But many health workers did not feel supported by leadership and felt psychologically unsafe, and some even faced negative repercussions (311).

The pandemic raised several liability concerns relevant to leadership and governance (*312, 313*). Some liability concerns were related to application of protocols and therapies based on little or no evidence of efficacy; infections in situations of inadequate PPE; and outbreaks in long-term care facilities and care homes. The pandemic also highlighted the need for more robust, systemwide safety governance for enabling risk management approaches to prevent and reduce patient harm across the health system. There was a need to revisit existing policies, regulations and standards (314). Several activities for responding to the COVID-19 pandemic needed high-reliability principles for organizational changes to improve patient safety. These included capacity-building, establishing a positive safety culture, escalating safety and guality improvement activities rapidly, and implementing teamwork principles, all of which require resource allocation and financial investment. Direct and indirect impacts of unsafe care have high financial and economic costs (315). COVID-19 has provided clear and compelling evidence of the need for financial investment and resource allocation to improve safety.

There has been a substantial financial impact on health care, and the health care system is more vulnerable than ever to financial instability (*316*). There have been staff shortages, layoffs, furloughs, and decreased funding for improvement, preparedness and innovation, all of which impact patient safety negatively (*317*). More recently there have been resignations, adverse staffing ratios, mandatory overtime, and decreased morale among health workers (*318*). In addition, claims for financial compensation for occupational diseases and injuries have significantly increased, mainly for COVID-19 cases among health workers (*319*).

Evidence reaffirms that governments, health systems and providers need to consider how "safety strategies, programmes and interventions can be implemented in a context of limited resources to generate the best value and return on investment" (315).

4.5 Communication and management of health information

4.5.1 Risks and harm from an infodemic of incorrect information

Rapid information spread has been one of the hallmarks of this pandemic. However, not all the information that is being spread is accurate or reliable. An infodemic is an overabundance of information – some accurate and some not – that occurs during an epidemic and travels between humans via digital and physical information systems (320). The spread of false information has been a serious negative consequence of the pandemic, with harm to patients and the public. It has played a powerful and damaging role in an era of easy global communication, often amplified through social media. Both misinformation (shared without malice) and disinformation (spread with the intent to deceive) occurred, leading to the spread of false ideas. Often misinformation and disinformation was spread to people and communities who are harder to reach, and those who are more vulnerable to begin with ([Evanega S, Lynas M, Adams JKS], [Cornell University], unpublished manuscript, [19 October 2020]).

Misinformation and disinformation about COVID-19 continue to pose a substantial threat to public health, with potential impacts on patient safety and public behaviour across the globe ([Evanega S, Lynas M, Adams JKS], [Cornell University], unpublished manuscript, [19October 2020]). People who are misled or misinformed by unsubstantiated or false claims are less likely to follow official health guidance to protect themselves and others. For instance, early in the vaccine roll-out phase of the pandemic, WHO alerted the global community to the risks of a distortion of facts that sowed unwarranted fears and distrust about vaccines and lowered vaccine acceptance from misperceptions about vaccine safety and efficacy, leading to more virus transmission and deaths (321). This also probably led to less adherence to mask-wearing protocols (322) and a distrust of public health authorities.

Misinformation and disinformation have both physical and psychological consequences for individual patients (323, 324). People attempted harmful "cures" due to misinformation about treatments. In a United States survey conducted in June 2020, 12%, 18%, and 18% of Americans respectively had dubious beliefs related to disinfectants, hot or humid climates, and hydroxychloroquine (325). During January-March 2020, poison control centres in the United States received 45550 exposure calls related to cleaning agents (28 158) and disinfectants (17 392), representing overall increases of 20.4% and 16.4% from the same time periods in 2019 and 2018 respectively (326). A CDC survey in the United States with 502 adults found that 39% engaged in dangerous practices, including washing food products with bleach, applying household cleaners directly to skin, and intentionally inhaling or ingesting disinfectants with the aim of preventing COVID-19 infection (327).

The misinformation accompanying the COVID-19 pandemic has caused hundreds of fatalities (*328*). In the Islamic Republic of Iran, a rumour that alcohol kills COVID-19 led many Iranians to drink counterfeit alcohol containing toxic methanol. As a result, over 300 people died, over a thousand required hospitalization and many will have permanent vision loss. Misinformation related to the use of hydroxychloroquine increased risk because of its adverse effects on the heart, seizures, hypokalaemia, and death. This also led to poisoning-related fatalities and critical illnesses (*329, 330*).

Not only did misinformation have safety consequences for patients and the general public, but it also led to serious security risks for the health workforce and scientists who were harassed, threatened and accused (331). This included threats on social media as well as verbal and physical abuse.

The COVID-19-related infodemic and disinformation has been a threat to the successful COVID-19 vaccination campaign. Several innovative approaches have emerged to proactively counter this. These approaches include getting those opposed to vaccination ("antivaxxers") (332) involved in the discussion, detecting fake news on the COVID-19 vaccine from YouTube videos using advanced machine learning approaches (333), innovative strategies to promote equity in the COVID-19 vaccine uptake for specific communities (334), specific psychosocial intervention for COVID-19 vaccine hesitancy among perinatal women in low-and middleincome countries (335), and monitoring and responding to public attitudes and behaviour towards the COVID-19 vaccine ([Biswas M, Ali H, Ali R, Shah Z], [Cornell University] unpublished manuscript, 20 January 2022]).

4.5.2 Health data and information management

While during a pandemic, reliable and accurate data are needed for epidemiologic assessment and to deliver safe and high-quality patient care, several health systems, public health agencies and governments relied on outdated or inadequate health data and information management systems during the pandemic (336).

Vulnerabilities related to limitations in health data and information management persisted throughout the pandemic, often related to how health data are captured and analysed. Many of the gaps related to local, national, and global health and public health information systems and data infrastructure were of long standing nature, but were felt prominently during the pandemic (337). Across several countries and health care settings, there was a dearth of reliable, timely and accurate data for evidence-based decision-making and actions (305).

While many countries believed their information systems worked reasonably well to address needs during the COVID-19 pandemic, critical gaps emerged, such as under-resourced public health services, outdated health information technologies, and a lack of interoperability (*338*). Information management challenges involved difficulties with case identification and reporting; syndromic surveillance; electronic laboratory reporting; and contact tracing. In addition, health care data are often separated from public health-related data, and no integrated picture emerges.

Some countries struggled with how to manage the pandemic without patient electronic health record systems. Even though some countries had such record systems, they did not have a well connected national information system to enable health officials to answer critical questions, such as how many COVID-19 patients are in a given geographical area, their age, and race; how many are hospitalized; how many are in intensive care, on ventilators, or have recovered or died; and how many of them experienced harm in health care (*339*).

Most countries and health care facilities do not have any systematic mechanisms for gathering and reporting data related to safety events and near misses. Comprehensive measurement of patient safety beyond incident reporting (113) had not been achieved in most health care organizations by 2014 (340). While certain individual health care facilities may gather safety data, they are mostly used for internal purposes and not all are aggregated and acted upon for wider learning and improvement. Similarly, clinical information systems may exist at the health care facility level but are not always used to provide real-time patient safety surveillance and improvement (62). Lack of reliable and timely safety data thus poses substantial challenges for decision-making and actions during the pandemic.

The pandemic underscores the need for a national and global health information infrastructure for timely, accurate, and reliable health information – a comprehensive, knowledge-based system capable of providing critical information to make sound decisions in emergency situations (*339*). For instance, VigiBase is a WHO global database of reported potential side-effects of medicinal products that was leveraged for monitoring vaccine safety (*341, 342*).

4.6 Development and supply chain of medical products, vaccines and technologies

The pandemic raised concerns about both the global and local supply chains in the United States of medical products (such as PPE and pharmaceuticals) and vaccines and technologies (343). In India, reported shortages also included testing and cleaning supplies, dialysis materials, ventilators, oxygen (344), and other medical supplies for patients with and without COVID-19. Such shortages placed patients at risk of harm due to care delays, rationing or denial of care, and use of substandard and falsified medical products (345).

In the United States, in addition to the reduced ability to manufacture products, the pandemic created a shortage of inputs such as raw materials and other components (*346*). Unequal distribution and demand surges also occurred, which were sometimes based on media coverage or emerging evidence of potential benefit. Several essential medicines experienced limited supplies. Some pharmacies closed due to the pandemic, and widespread illness, quarantines, and social distancing measures disrupted pharmacy access (*347*) for many in need. Hospitals experiencing a surge often struggled to maintain supplies of antibiotics, antivirals, sedatives and anaesthetics, especially when supplies were dependent

on countries where the pandemic slowed down manufacturing (347, 348). Some care sites depended on lengthy transportation routes that were easily disrupted.

In certain places, medication shortages have had implications for non-COVID-19 patients too. A global shortage of tocilizumab (used for COVID-19) has affected patients with rheumatoid arthritis (349). Generic medicines of several types have been experiencing shortages because of reliance on a few countries that help produce them. Few places have been prepared for such emergencies and most have had no established centralized inventories of essential medicines that could be mobilized (350).

The pandemic has also impacted the development of medical products, vaccines and technologies, and new drugs and discoveries. In addition, there were reports of COVID-19 vaccine doses being destroyed as they were near expiry dates; this vaccine wastage occurred in both developed and developing countries (*351*). There has been a serious and disruptive effect on the conduct of clinical trials, with both immediate and delayed consequences (*352*). For instance, while trials testing treatments for COVID-19 have been prioritized, there has been a collateral negative effect on other trials needed for other potentially lifesaving therapies (*190*). Long-term consequences for patient safety of delays and disruptions of clinical trials need to be further researched.

Key considerations

5.1 Summary of the findings

The rapid review finds that risks and avoidable harm from the COVID-19 pandemic are highly prevalent, and many of the risks and harms are common across many countries. A range of safety gaps have been revealed across all core components of health systems and at all levels. While a robust foundation of basic safety principles has been absent in health care settings across the globe and patients were already at significant risk of harm in health care prior to the COVID-19 pandemic, lessons from the pandemic have emphasized the need to prepare for safer and more resilient health systems (353, 354). Health systems in nearly all countries, but especially lower- and lower-middle-income countries (355), are experiencing greater challenges from limited public health infrastructure and the diversion of essential medical resources.

The safety gaps identified provide the evidence needed to inform the development of more resilient health systems, with the capacity to adapt to challenges and changes at different system levels, to maintain safe and high-quality care (*356*). The key observations from this rapid review are summarized below.

 The COVID-19 pandemic revealed a range of safety gaps across all core components of health systems, at all levels. The pandemic exposed vulnerabilities related to provision of health services; leadership; governance and financing; communication and management of health information; and development and supply chain of medical products, vaccines and technologies. Issues related to the health and safety of health workers, to the engagement of patients, families and communities, and to inequities in care and outcomes were also prominent. High risk of avoidable harm occurred at the point of care due to several reasons, including inadequate infection prevention and control measures, water, sanitation, and hygiene practices, and infrastructure; increased risk of health care-associated infections; surgical safetyrelated concerns; antimicrobial resistance; misuse and overuse of antibiotics; medication errors and unsafe medication practices; increased incidence of pressure injuries and patient falls; diagnostic errors; and medical product supply issues.

- 2. The risks and magnitude of avoidable harm from the COVID-19 pandemic still need to be understood. The precise burden of risks and avoidable harm during the pandemic has not yet been fully assessed, as current systems for measurement and surveillance of patient safety are not well developed and data on the burden of risks and avoidable harm are limited across and within countries. Several short-term and long-term impacts of the pandemic on patient safety are still unfolding.
- 3. Disruptions to systems and processes of care affected previously known safety risks and sources of harm in health care and introduced new ones. The pandemic has profoundly impacted nearly all countries' health systems and diminished their capability to provide safe health care, specifically due to errors, harm and delays in diagnosis, treatment and care management. The pandemic led to worsening of known safety risks, with an increase in health care-associated infections and increased risk of medication errors. It also resulted in the introduction of new types of errors and delays in diagnosis of both COVID-19 and non-COVID-19 conditions; increased incidence of mental health

issues; and delays in treatment of other serious conditions.

- 4. The capacity of health systems to continue the delivery of essential health services has implications for patient safety. The pressures and urgent demands on health systems revealed serious gaps in their resilience, which generated risks to both patients and health workers. Diagnostic and treatment delays occurred because of the substantial disruptions across all major health areas, such as communicable and noncommunicable diseases, neglected tropical diseases, immunization, reproductive, maternal, newborn, child and adolescent health, and nutrition.
- 5. Managing COVID-19 in countries experiencing fragility, conflict and violence has been even more challenging. These include unstable social and economic conditions, weak governance and state institutions, limited access to services for vulnerable populations, increases in workplace violence, and lack of trust in the health care system.
- 6. The pandemic caused substantial disruptive impacts on the health workforce. Health care systems across the world have been overwhelmed and overextended under the extreme pressure, and health workers have been working tirelessly in these unforeseen and difficult circumstances. Staff shortages, staff redeployment to unfamiliar roles, and the physical and mental health and security of health workers have all disrupted existing care processes in most health systems worldwide. The increased workload and stresses in pandemic situations has made health workers more prone to making errors, consequently impacting patient safety, due to long working hours, fatigue, burnout, psychological distress, and ineffective communication and care coordination amongst the health workers.
- 7. **Misinformation and disinformation have been prevalent during the pandemic.** These can be a source of harm to patients and the public and may erode public trust in science, posing a substantial threat to public health with potential impacts both on patient safety and public behaviour, including COVID-19 vaccine uptake.
- 8. Safety and equity are inextricably linked, and the pandemic exposed long-standing structural drivers of health inequities and gaps

in outcomes for certain population groups. Although the COVID-19 pandemic affected all population groups, there were differential exposures, safety risks and vulnerability, and differential health outcomes and non-health-related consequences of the pandemic – largely due to the social determinants of health and pre-existing chronic conditions (*357*).

- 9. Interaction between patients and families and health workers was severely constrained. Many health services became virtual, potentially compromising the quality of patient and family engagement and patient safety in certain circumstances. Moreover, families were unable to provide support to their family members because of social distancing restrictions and visitation policies, and the diminished safety net for prevention of errors and avoidable harm.
- 10. While most of the consequences have been negative, several positive developments have also occurred. These include transformational changes in leadership and culture; new communication channels and data exchanges; innovative crisis management programmes, protocols, and care pathways; rapid development of new diagnostic tools and technologies as well as vaccines, diagnostics and therapeutics; rigorous and rapid staff training; raised awareness about mental health and the importance of caring for health workers; increased public interest in health matters; increased understanding of hospital infrastructure and the architectural design of health care facilities: digital innovations and telemedicine; and generation of scientific evidence, including through implementation science research.

5.2 Limitations

Data on burden of risks and avoidable harm are limited across and within countries. The rapid review therefore addresses certain more easily measurable concepts in depth, while safety problems that are not easily measured are not included and not discussed in this review.

There are limitations related to the scope of the literature found and reviewed. Several studies are based on a single site or single country. Data from low- and middle-income countries are limited.

5.3 Opportunities to build on lessons learned from the pandemic

Significant opportunities lie ahead for patient safety improvement in the context of the pandemic. Many instances of risks and avoidable harm identified in this rapid review are still ongoing and if unaddressed are likely to prevail again no matter what pathogen the next pandemic will involve. These include risks and avoidable harm from lack of adequate infection prevention and control measures, water, sanitation, and hygiene practices and infrastructure, diagnostic errors or delays, medication errors, overloaded health systems, an overburdened workforce, the weakening of preventive interventions, the failure to obtain or receive recommended care, and deficiencies in caring for patients. Additional research is needed in specific risks and safety areas, and more work is required to identify best practices and lessons learned to inform optimal interventions and recommended next steps, and in the long term to contribute to building safer and more resilient health systems. Meanwhile, the findings of this rapid review provide the foundational knowledge needed to mount a robust response to mitigate the impact of the ongoing and next public health emergency and to reduce the risk of avoidable harm (358-361).

While most of the implications described herein have been negative, several positive developments have also occurred and could be an impetus for change going forward. The world has never been as united to fight a common enemy (26). Now is an opportunity to build on several advances, such as the development and implementation of care pathways and guidelines, digital innovations, increasing transparency, open and frequent bidirectional communication, data sharing, collaboration and teamwork with the breakdown of traditional silos, and the rapid adoption of selected patient safety practices. These advances led to short-term benefits that now need to be sustained. Sustaining changes and enabling further progress require robust implementation strategies, and a consideration of the human aspects of managing change (362).

Scaling up protection of the health, safety and well-being of health workers needs development, and should include the implementation of comprehensive sustainable programmes for occupational health and safety in the health sector – at national, subnational and health facility levels. Such programmes should function in synergy with patient safety, infection prevention and control, and other health workforce programmes (215, 363).

There is an opportunity after this crisis to embed these positive changes into the design and development of health care systems, products and processes to ensure that safety is at the core of health and social care systems globally. Positive results and practices should be observed and supported, while simultaneously monitored for emerging risks and additional gaps.

What is needed is a multidisciplinary approach that is founded on multiple disciplines important to patient safety (*364*) and that could yield lessons to inform the development and implementation of patient safety strategies and innovations for a safer health care system. This will require new policies that strengthen interactive components of the complex adaptive health care system, solidify public health linkages, and ensure global cooperation (*365*). Post-pandemic health systems will also need to be prepared for unexpected and emerging threats, and will need to address current structural inequities (*366*).

The recently developed WHO Global Patient Safety Action Plan 2021–2030 provides a comprehensive framework to address the safety gaps identified. The strategies provided in the global action plan will be instrumental in implementing high-reliability principles, developing a culture of safety, improving patient safety in emergencies and outbreaks, empowering patients and families, and educating and protecting health workers (5). These strategies will also lead to strengthening resilience, leveraging patient safety and quality improvement science (56), and using the skills of patient safety and quality improvement professionals to build a safer health care system that minimizes harm to patients and health workers.

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